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|  | | Department/Division/Office/  Unit | DFAR Department/HMDAR Division | |
| Document Type: **Form** | | | Doc. No | :DFAR/HMDAR/FOM/022 |
|  | | Title:  **Application Form for Medical Devices and In Vitro Diagnostics Devices (IVDDs) registration** | Revision Number | : 2 |
| Revision Date: | : 17/10/2022 |
| Effective Date | : 31/10/2022 |
| Review Due Date | : 30/10/2025 |
| Ref Doc. | : |
| **Application Number** | | **Rwanda FDA use only** | | |
| **Date of submission of dossier** | | **Rwanda FDA use only** | | |
| 1.0 PARTICULARS OF THE MEDICAL DEVICE or IVDD (**Bold or Tick** the right type of application) | | | | |
| 1.1 | Type of application   New  full registration abridged registration   Renewal   Variation\*  \* If variation has been made, information supporting the changes should be submitted. | | | |
| 1.2 | Name of the Medical Device or IVDD | | | |
| 1.3 | Classification of the Medical Device or IVDD | | | |
| 1.4 | Intended use of the Medical Device or IVDD | | | |
| 1.5 | Name and address (physical and postal) of Applicant  Address:  Country:  Telephone:  Telefax:  E-Mail: | | | |
| 1.6 | Name and address ( physical and postal) of the manufacturer  Address:  Country:  Telephone:  Telefax:  E-Mail | | | |
| 1.7 | Visual description of the Medical Device or IVDD | | | |
| 1.8 | Proposed shelf life (in months) (where applicable): | | | |
| 1.9 | Proposed storage conditions (where applicable): | | | |
| 1.10 | Other sister/variants of the medical device (s) or IVD (s) registered or applied for registration | | | |
| 1.11 | list all accessories that are manufactured/ sold with the devices | | | |
| 1.12 | Do you hold Marketing Authorization(s) for another/ other medical device(s) or In Vitro Diagnostics Devices (IVDDs) in any of the East African Community (EAC)?   Yes   No  If yes state Medical Device(s) or IVDD(s) name:  Regulatory Authority(ies) where the product is authorized:    Marketing authorization number(s):  Indication(s): | | | |
| 1.13 | Have you applied for Marketing Authorization(s) of medical device(s) or In Vitro Diagnostics Devices (IVDs) in any of the countries of the East African Community (EAC)?   Yes   No  If yes state  Medical Device name or IVDD:  Regulatory Authority(ies) where you have applied for registration:  Indication(s): | | | |
| 1.14 | Country of origin (where the device was manufactured) | | | |
| 1.15 | Device Marketing Authorization in the country of origin (Attach Marketing Authorization of the Medical Device or IVDD from the National Regulatory Authority). If not registered, state the reasons   |  |  | | --- | --- | |  Authorized Country:  Date of authorization:  Authorization number:   Refused Country:  Date of refusal:  Reason for refusal: |  Withdrawn (by the applicant after authorization) Country:  Date of withdrawal:  Reason for withdrawal:   Suspended/revoked (by competent authority) Country:  Date of suspension/revocation:  Reason for suspension/revocation: | | | | |
| 1.16 | Name(s) and physical address(es) of the manufacturing site(s) of the Medical Device or IVDD. Alternative sites should be also declared here.  All manufacturing sites involved in the manufacturing process of the device, stating the role of each including the quality control / in-process testing sites should be listed.  Address:  Country:  Telephone:  Telefax:  E-Mail: | | | |
| 1.17 | Name and address (physical and postal) of the Agent/Local Technical Representative (LTR) (Attach a valid appointment letter notarized from the country of origin):  Address:  Country:  Telephone:  Telefax:  E-Mail: | | | |
| 1.18 | Name and address (physical and postal) of the person or company responsible for Pharmacovigilance and Post Marketing Surveillance:  Address:  Country:  Telephone:  Telefax:  E-Mail: | | | |
| 1.19 | Declaration of Conformity specifying all standards used in the manufacturing of the Medical Device or IVDD | | | |
| 1.20 | Qualitative and Quantitative composition of the Medical Device or IVDD (If applicable) | | | |
| 1.21 | Name and address (physical and postal) of the Contract Research Organisation(s) where the clinical studies of the Medical Device or IVDD were conducted. (If applicable)  Address:  Country:  Telephone:  Telefax:  E-Mail: | | | |
| 2.0 DECLARATION BY THE APPLICANT | | | | |
| I, , the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge.  I further confirm that the information referred to in my application dossier is available for verification during the Quality audit inspection. I also agree that I shall carry out pharmacovigilance and Post-marketing Surveillance to monitor the safety, quality and performance of the device on the market and provide safety, quality and performance update reports to Rwanda FDA.  I further agree that I am obliged to follow the requirements of Rwanda's Legislation and Regulations, which are applicable to Medical Devices and IVDDs. I also consent to the processing of information provided to Rwanda FDA. It is hereby confirmed that fees will be paid/have been paid according to the authority’s rules\*  Signature:  Date:  \* **Note**: If fees have been paid, attach proof of payment | | | | |